

REMARKS

I. In item 4 on page 2 of the Office Action, the drawings were objected to for a variety of reasons.

Attached hereto are four sheets of formal drawings that were submitted in the corresponding PCT application. Accordingly, the objection can be withdrawn.

II. In item 6 on page 3 of the Office Action, claims 1, 3-8 and 11-17 were rejected under 35 U.S.C. 112, second paragraph for a variety of reasons.

The various issues raised by the Examiner are discussed and traversed seriatim.

The Examiner raised an issue with regard to claim 1.

Claim 1 now recites that a variant of GAVE3 is one that retains a GAVE3 function. The instant specification provides a thorough teaching of the various GAVE3 functions, as well as the methods and means for making GAVE3 variants and identifying whether a variant retains a GAVE3 function. As artisan would well recognize the metes and bounds of claim 1.

As to claim 5, the Examiner again raised an issue regarding the variants of interest.

Claim 1 relates to a variant of GAVE3 that retains a GAVE3 function. Claim 5 properly depends from claim 1, relating to a variant having a GAVE3 function of claim 1. Hence, proper antecedent basis exists.

Next, with respect to claim 6, said claim was amended to clarify the language within. The appropriate conservative amino acid substitutions are taught in the paragraph bridging pages 14 and 15 of the instant specification.

In the paragraph bridging pages 3 and 4 of the Office Action, the Examiner raised an issue with claim 7.

The instant specification provides a thorough description of stringent hybridization conditions. Claim 7 was modified to clarify and to track the particular teachings of the instant specification.

Finally, in the first full paragraph on page 4 of the Office Action, claim 8 was discussed.

The grammatic error relating to the pronoun was corrected as well as the reference to the appropriate sequence identifier.

In view of the amendments to the claims and the arguments hereinabove, the bases for the rejection are no longer tenable, the claims are distinct and formally proper and thus, the rejection must be removed.

III. In item 8 on page 4 of the Office Action, claims 1, 3-8 and 11-17 were rejected under 35 U.S.C. 112, first paragraph for an alleged want of enablement.

The various issues are discussed and traversed in turn.

The Examiner first raised the issue that a claimed nucleic acid may not encode an active protein.

However, the claimed polynucleotides are those of SEQ ID NO:1 or variants thereof that encode a polypeptide that possesses a GAVE3 function. The instant specification clearly teaches how to make and how to identify such variants at the nucleic acid and polypeptide levels, and to ascertain whether a GAVE3 function exists in a variant.

With respect to claim 4, the Examiner queried whether an artisan would know where to find variants of GAVE3.

The instant specification clearly teaches how to make, to identify and to use nucleic acids and proteins that have high levels of GAVE3 sequence homology and/or GAVE3 functional homology. Clearly, molecules of high homology will include allelic variants.

Moreover, an artisan, when surveying a population, can readily identify allelic variants by changes in the GAVE3 nucleic acid and/or amino acid. That knowledge is well within the ambit of the artisan of ordinary skill in the art. That

exercise is not burdensome, is routine experimentation known in the art and does not entail undue experimentation.

With respect to claim 7, the claimed nucleic acid encodes a polypeptide with GAVE3 function and that claimed nucleic acid hybridizes to a particular GAVE3 probe, wherein the nucleic acid of interest and the probe are at least 55% complementary.

The instant specification teaches molecules, whether nucleic acid or protein, which vary from the particular nucleic acid and amino acid sequence of GAVE3, and also teaches how to identify whether any such variant of GAVE3 retains a GAVE3 function.

In the paragraph bridging pages 7 and 8 of the Office Action, the Examiner thought that it is unpredictable as to what portions of a molecule may be antigenic.

The instant specification teaches those specific portions of GAVE3 which are present at the cell surface, are present within the membrane and are present in the cytoplasm. The instant specification also teaches how one can use antibodies as probe of the extracellular domains to determine those antibodies that bind to GAVE3 and to which portions thereof. Thus, the instant specification provides a thorough teaching of how to make and how to use antibodies with GAVE3, and how to identify variant amino acids of GAVE3 at the cell surface.

Hence, while the Examiner has raised issues that might require

experimentation, the level of experimentation is routine irrespective of the time to execute that routine experimentation. Accordingly, the Examiner has not made a prima facie case of non-enablement.

The instant specification clearly defines and teaches the making, identifying and using of variants and determining whether those variants have a GAVE3 activity or function. In view thereof, the specification and claims are in full compliance with 35 U.S.C. 112 and withdrawal of the rejection is in order.

IV. In item 9 on page 9 of the Office Action, claims 1, 3-8 and 11-17 were rejected under 35 U.S.C. 112, first paragraph for an alleged want of written description.

The rejection is traversed for the following reasons.

The instant specification provides a thorough disclosure and description of the nucleic acids and variants thereof that encode a polypeptide with GAVE3 function and activity. An artisan on reading the instant specification clearly would know what molecules are encompassed by the specification and claims, and would clearly know that the instant invention relates to GAVE3 as well as variants thereof that retain GAVE3 function. The nucleic acids of interests have a clearly defined function that provides a common basis of identification of the molecules of interest.

Hence, the instant specification clearly describes the invention of interest and an artisan would well recognize that the claimed invention was not only described in the disclosure but also clearly and fully was in the possession of the inventors when the

application was filed. Accordingly, withdrawal of the rejection is in order.

V. In item 11 on page 11 of the Office Action, claims 1-8 and 11-17 were rejected under 35 U.S.C. 102(a) over WO 01/36473.

The rejection is traversed for the following reasons.

The disclosure relied on by the Examiner does not satisfy the standards of enablement of a reference. Hence, the rejection is improper and must be removed.

VI. In item 12 bridging pages 11 and 12 of the Office Action, claims 1, 3, 5-7 and 11-17 were rejected under 35 U.S.C. 102(b) over WO 98/56820.

The rejection is traversed for the following reasons.

The '820 application discloses the HM74A molecule which is different from GAVE3. According to the documents provided by the Examiner, full length HM74A has only 48% amino acid identity and 3% nucleic acid identity to GAVE3.

The instant invention relates to GAVE3 and molecules with GAVE3 function. Thus, the cited reference does not anticipate and does not teach the claimed invention. Accordingly the rejection is improper and must be removed.

Applicant: Tai-He XIA et al.
Application No. 09/866,041
Attorney Docket No. 2101976-991210
(formerly 41491)

CONCLUSION

Applicants submit that the examined claims are in condition for allowance. Reexamination, reconsideration, withdrawal of the objection and rejections, and early indication of allowance are requested respectfully. If any questions remain, the Examiner is urged to contact the undersigned at the local exchange noted below. If any fees are found to be applicable, please charge any additional fees or make any credits to Deposit Account No. 07-1896.

Respectfully submitted,



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